REMARKS

The pending Office Action addresses and rejects claims 1-27.

Rejection Pursuant to 35 U.S.C. §103

Fonger and Purdy

The Examiner rejects claims 1-11, 13, and 15-27 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent 5,291,896 to Fonger et al. ("Fonger") in view of U.S. Publication 2003/0097082 to Purdy et al. ("Purdy"). The Examiner argues that Fonger teaches the claimed invention except for "(a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna." The Examiner relies on Purdy to teach these features, arguing that it would have been obvious to modify the device of Fonger in view of Purdy to arrive at the claimed invention. Applicant respectfully disagrees.

Independent claim 1 recites an implantable fluid management device having an elongate catheter, a sensor embedded in a distal portion of the catheter, and at least one wire having a distal end coupled to the sensor and a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor.

In response to Applicants' arguments, the Examiner asserts that:

> ...the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Fonger, Purdy, and Quackenbush all teach implantable fluid management devices (i.e. medical catheters) and methods of use thereof.

In other words, the Examiner appears to be asserting that because "Fonger, Purdy, and Quackenbush all teach implantable fluid management devices," this alone provides the requisite motivation to combine.

Applicants acknowledge that Fonger, Purdy, and Quackenbush are all directed to medical catheters, but this alone is not enough to establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, the Office Action must meet three criteria:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.[1]

It would not have been obvious to modify the device of Fonger to include a distally disposed pressure sensor embedded in a distal portion of the catheter.

First, Fonger already provides a sensor located on a probe extending from a tube, thus there is no need to make the modification suggested by the Examiner. Further, such a modification would change the principal operation of the Fonger device. MPEP 2143.01(VI) states that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." The basic principle of Fonger is to provide a probe with tines for attaching a pressure sensor on the probe to a blood vessel. The probe is specifically configured to extend from a tube to allow the probe to attach to a vessel. Modifying the device to put the sensor on the tube, rather than the probe, changes the principle operation of the device. Moreover, such a modification would render the Fonger device inoperable. MPEP §2143.01(V) states that "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." If the device of Fonger were modified to include a sensor embedded in a sidewall of the tube (12), as suggested by the Examiner, then the sensor could not be used for its intended purpose. Namely, if the sensor were located on the tube it could not be attached to an external surface of a blood vessel to measure cardiac output.

Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over Fonger and Purdy, taken alone or combined, and represent allowable

[1] *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

subject matter.

Independent claim 18 recites an implantable fluid management device having an elongate catheter, a sensor disposed at a distal portion of the catheter, at least one wire extending through the catheter, and a slit extending through an outer wall of the catheter. The at least one wire has a distal end that is coupled to a sensor and a proximal end that is mated to an external antenna.

One having ordinary skill in the art would not be motivated to modify the device of Fonger to include an antenna as taught by Purdy. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP §2144). There is no advantage to modifying the cardiac output probe of Fonger to include an antenna as taught by Purdy because there is no need to remotely communicate with or energize the detector of Fonger. As explained at Col. 4, lines 26-32 and 50-55, Fonger discloses a *temporary* cardiac output probe assembly for measuring and monitoring cardiac output during the post-operative recovery period following open heart surgery. Since the Fonger probe is specifically designed for in-hospital use when the patient is under the direct supervision of a physician, there is no need to modify Fonger to include an antenna for remote communication, as taught by Purdy.

Accordingly, independent claim 18, as well as claims 19-27 which depend directly or indirectly therefrom, distinguish over Fonger and Purdy, taken alone or combined, and represent allowable subject matter.

Fonger, Purdy, and Quackenbush

The Examiner rejects claims 12 and 14 pursuant to 35 U.S.C. §103(a) as being obvious over Fonger in view of Purdy further in view of U.S. Patent 5,104,398 to Quackenbush ("Quackenbush"). The Examiner argues that Fonger and Purdy teach the claimed invention except for "the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and wherein the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter." The Examiner relies on Quackenbush to teach these features, arguing that it would have been obvious to modify the devices of Fonger and Purdy in view of Quackenbush to arrive at the claimed

invention. Applicant respectfully disagrees.

Claims 12 and 14 depend from independent claim 1. As explained above, one having ordinary skill in the art would have no motivation to combine Fonger and Purdy. Quackenbush does not provide any supplemental motivation because Quackenbush merely discloses a splittable tube. Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over Fonger, Purdy, and Quackenbush, taken alone or combined, and represent allowable subject matter.

Conclusion

In conclusion, Applicant submits that claims 1-27 are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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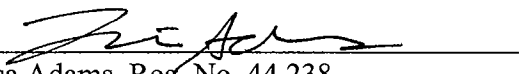

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